K011196

NOV 0 8 2001

IQuantify Workstation
Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness Information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

Submitter:
Insightful Corporation
1700 Westlake Ave. N, Suite 500
Seattle, WA 98109
Tel: (206) 283-8802

Date Prepared: April 5, 2001

Contact:
Brad Wyman, Ph.D.
Research Scientist
Tel: (206) 283-8802 x256

Device Trade Name: IQuantify Workstation, Version 1.0

Device Common Name: Medical Image Processing Software

Substantially Equivalent To:

GE Advantage Windows (AW) 4.0 Workstation

AW Basic Viewing Workstation	K913770
AW 3D Viewing Option	K963345
AW Fusion	K983256

GE Medical Systems
P.O. Box 415
Milwaukee, WI 53201

Able Software 3D-DOCTOR
K003746
Able Software
5 Appletree Lane
Lexington, MA 02420
Diagnostic Viewer

Device Description:
IQuantify is a medical image workstation designed for display and evaluation of 2D or 3D images from different image modalities such as MRI, CT, PET, and ultrasound. IQuantify can register images from the same or different modalities (ie CT/MRI) and can assist the user in segmenting tissues. Tools for segmenting include user trained multi-modality segmentation, seed growing methods and active contouring. In addition tools are provided

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for visualizing and editing the segmentation results. Once a tissue is segmented quantification of the volume and tissue dimensions can be made.

Intended Use:
IQuantify version 1.0 is intended for the visualization, storage, processing and analysis of 2D and 3D multimodality medical images from imaging modalities such as MRI, CT, PET, and ultrasound. IQuantify provides capabilities for registering images and assisting the user in segmenting and contouring tissues. Segmented regions can subsequently be quantified.

Comparisons with Predicate:

System	**IQuantify 1.0**	**GE, Advantage Workstation**
510(k)		K913770, K963345, K983256
Feature	Image display and multiplanar reconstruction of multi-modality 2D/3D data.	✓
	Data archive.	✓
	Data analysis	✓
	Volumetric/surface analysis of data	✓
	Interactive multi-facet definition of lesions	✓
	Segmentation	✓
	Automates manual measurements	✓
	Registration of multi-modality images	✓
Intended Use	Tissue volume definition/quantification.	Oncology-tumor Volume definition/quantification
Data Source	DICOM formatted images	DICOM formatted images
Physical Characteristics	• Software Package • Operates on off-the-shelf hardware • NT Operating system • DICOM compatible	• Software Package • Operates on Advantage Windows Workstation • DICOM compatible
Safety	Clinician interactive review/editing of data is integral to the use of the tool.	The tool measures and displays the volume of outlined images. Outlined images can be modified accepted or rejected by the clinician

Summary of Studies:
IQuantify will be fully verified/validated per the program test plans.

Conclusion:
The IQuantify 1.0 Workstation provides 3D visualization and quantification of tissues from multiple image modalities. The potential hazards are controlled by a risk management plan including:

- Hazard analysis
- Software development and validation process
- Software verification plan
- User interaction and ability to edit the end results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2001

Bradley T. Wyman, Ph.D.
Research Scientist
Insightful Corporation
1700 Westlake Avenue North
Suite 500
SEATTLE WA 98109

Re: K011196
Trade/Device Name: IQuantify Version 1.0
Image Processing System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving
and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 9, 2001
Received: August 10, 2001

Dear Dr. Wyman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k) Number (if known):____K011196_____

Device Name: IQuantify, Version 1.0

Indications For Use:

IQuantify version 1.0 is intended for the visualization, storage, processing and analysis of 2D and 3D multimodality medical images from imaging modalities such as MRI, CT, PET, and ultrasound. IQuantify provides capabilities for registering images and assisting the user in segmenting and contouring tissues such as: gray matter, white matter, cerebral spinal fluid (CSF), cardiac, prostate, and lesions. Segmented regions can subsequently be quantified.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
Per 21 CFR 801.109

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011196